

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s) : Robert A. LEVINE et al.
Appln. Serial No. : 10/523,096
Filed : August 31, 2005
Entitled : CARDIAC DEVICES AND METHODS FOR MINIMALLY
INVASIVE REPAIR OF ISCHEMIC MITRAL
REGURGITATION
Group Art Unit : 3739
Examiner : Henry M. Johnson, III
Confirmation No. : 8398

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PRE-APPEAL BRIEF REQUEST FOR REVIEW AND ARGUMENTS

Sir:

As set forth in the 12 July 2005 New Pre-Appeal Brief Conference Pilot Program guidelines, this Pre-Appeal Brief Request for Review sets forth a succinct, concise and focused set of arguments for which the review is being requested. This paper is being filed contemporaneously with a Notice of Appeal and the request form PTO/SB/33. This paper is filed in response to the Final Office Action dated January 11, 2008 and the Advisory Action dated May 2, 2008.

CLAIM STATUS

In the Response to Final Office Action dated April 11, 2008, claim 1 had been amended merely to remove a minor informality and not for any reason relating to patentability thereof, and new claims 68 and 69 had been added to cover certain exemplary embodiments of Applicants' invention, support being found in the originally-filed specification and drawings. In the Advisory Action, the Examiner indicated that the amendment to claim 1 and new claims 68 and 69 would not be entered. Thus, previously presented claims 1, 2, and 56-67 are currently under consideration in the present application. At least, the amendment to claim 1 should have been entered as being made only for consistency purposes.

ARGUMENTS

I. REJECTIONS UNDER 35 U.S.C. §§102 and 103 SHOULD BE WITHDRAWN

Claims 1, 2, 56 and 57 stand finally rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,643,248 issued to Yoon (the "Yoon Patent"). Claims 1, 58, 59, 62 and 63 stand finally rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,957,863 issued to Koblish et al. (the "Koblish Patent"). Claim 61 stands finally rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the Koblish Patent. Claims 64-66 stand finally rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the Yoon Patent, and further in view of U.S. Patent No. 6,626,899 issued to Houser et al. (the "Houser Patent"). Claim 67 stands finally rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the Yoon Patent, and further in view of U.S. Patent Application Publication No. US 2002/0173811 to Tu et al. (the "Tu Publication").

Applicants respectfully assert that (i) the Yoon Patent fails to disclose, teach or suggest the subject matter recited in independent claim 1 and the claims which depend therefrom, (ii) the Koblish Patent fails to disclose, teach or suggest the subject matter recited in independent claim 1 and the claims which depend therefrom, and (iii) the Houser Patent and the Tu Publication fail to cure the deficiencies of the Yoon Patent and the

Kablsh Patent to teach or suggest the subject matter recited in independent claim 1 and the claims which depend therefrom.

As the panel is well aware, in order for a claim to be rejected as anticipated under 35 U.S.C. § 102, each and every element as set forth in the claim must be found, either expressly or inherently described, in a single prior art reference. Manual of Patent Examining Procedures, §2131; *also see Lindeman Maschinenfabrik v. Am Hoist and Derrick*, 730 F.2d 1452, 1458 (Fed. Cir. 1984).

Independent claim 1 recites an apparatus for treating atrioventricular valve regurgitation which includes, *inter alia*, **a cutting arrangement** configured to sever at least one chord attaching an atrioventricular leaflet to a internal cardiac muscle **and a grasping arrangement** configured to constrain the movement of a chord relative to the catheter. In particular, Applicants respectfully assert that none of the cited references disclose, teach or suggest both a cutting arrangement and a grasping arrangement, i.e. **two separate arrangements**. Rather, the Yoon Patent describes a hook, which the Examiner admittedly asserts on page 3 of the Final Office Action “serves as both a grasping and cutting means” (see *Final Office Action*, p. 3, lines 6-7), and the Koblish Patent describes jaws that work together to form a cutting member, which the Examiner asserts on page 3 of the Final Office Action inherently grasp and cut a biopsy sample and operate via a wire looped into the jaws, making the wire a part of the grasping member (see *Final Office Action*, p. 3, lines 13-16).

Further, the Examiner asserts on page 2 of the Advisory Action that a “[b]road interpretation of [independent] claim 1 does not require separate cutting and grasping members.” Advisory Action, p. 2. However, independent claim 1 clearly recites a cutting arrangement as one element and a grasping arrangement as another, separate element. Therefore, it is abundantly evident that independent claim 1 clearly recites a separate cutting arrangement and a separate grasping arrangement, contrary to the Examiner’s assertion in the Advisory Action.

Moreover, the hook described in the Yoon Patent and the jaws described in the Koblish Patent, each serving as both a cutting arrangement and a grasping

arrangement, preclude the ability to separately maneuver and adjust each of the two separate arrangements. As none of the cited references, taken alone or in combination, disclose, teach or suggest both a cutting arrangement and a grasping arrangement **as two separate arrangements**, as explicitly recited in independent claim 1, Applicants respectfully assert that none of the cited references, taken alone or in combination, disclose, teach or suggest all of the elements recited in independent claim 1.

Claims 2 and 56-69 depend from independent claim 1, and Applicants respectfully assert that these claims are also allowable over the cited references for at least the same reasons provided with respect to independent claim 1 above.

Accordingly, Applicants respectfully submit that the subject matter recited in claims 1, 2 and 56-69 is not disclosed, taught or suggested in any of the cited references, taken alone or in combination, and that the rejections of pending claims 1, 2 and 56-67 under 35 U.S.C. §§102 and 103 therefore should be withdrawn and dependent claims 68 and 69, which depend from independent claim 1, entered as amended in the amendment filed on April 11, 2008.

II. **REJECTION UNDER 35 U.S.C. § 112 SHOULD BE WITHDRAWN**

Claim 60 was finally rejected under 35 U.S.C. § 112, second paragraph as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. Specifically, the Examiner alleged that it is not clear how the acute angle is defined relative to the surface as the wire is essentially circular and presents multiple angles. However, the Examiner did not address this rejection in the Advisory Action dated May 2, 2008.

Applicants respectfully assert that the subject matter of claim 60 is in no way indefinite as asserted in the Final Office Action. As stated in paragraph [0037] of the present specification, for example, “[o]ther deformations in the wire suitable to grasp the chord 10, such as sharp to orthogonal bends or V-shapes, are possible.” (Applicants’ Specification, paragraph [0037]). Accordingly, Applicants respectfully assert that the rejection to claim 60 under 35 U.S.C. § 112, second paragraph should be withdrawn.

III. CONCLUSION

In light of the foregoing, Applicants respectfully assert that claims 1, 2 and 56-69 are in condition for allowance. Prompt reconsideration and allowance of the present application are therefore earnestly solicited. The Examiner and/or the panel are invited to contact the undersigned to expedite the prosecution of this application if any issues remain outstanding.

This Pre-Appeal Brief Request for Review is submitted contemporaneously with a Notice of Appeal. Accordingly, please charge Deposit Account No. 50-2054 in the amount of \$255.00 (small entity) for the Notice of Appeal fee. In addition, Applicants submit herewith a petition for a one-month extension of time under 37 CFR 1.136(a). Accordingly, please also charge Deposit Account No. 50-2054 in the amount of \$60.00 (small entity) for the petition fee. Applicants believe no further fees or petitions are required. However, if any such petitions or fees are necessary, please consider this a request therefore and authorization to charge Deposit Account No. 50-2054 accordingly.

Respectfully submitted,

Date: May 12, 2008

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